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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Application of | ) | |
| | ) | |
| Kenneth Brigham et al. | ) | |
| | ) | Art Unit: Unassigned |
| Serial No.: Unassigned | ) | |
| | ) | Examiner: Unassigned |
| Filed: Concurrent | ) | |
| | ) | |
| For: GENE DELIVERY AND EXPRESSION IN AREAS INACCESSIBLE TO DIRECT PROTEIN DELIVERY | ) | |

**PRELIMINARY AMENDMENT**

BOX PATENT APPLICATION
Commissioner for Patents
Washington, D.C. 20231

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December 20, 2001

Sir:

Prior to issuing an Office Action for the above-referenced patent application, kindly enter the preliminary amendments and consider the remarks provided below.

In the Specification:

On page 1 of the specification, please delete lines 6 through 12 and in their place insert:

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of, and claims priority to, U.S. Serial No. 08/951,552, filed October 16, 1997 (allowed), which claims priority to U.S. Serial No. 60/029,252, filed October 24, 1996, both of which are herein incorporated by reference in their entirety.--

In the Claims:

Please cancel claims 2 through 35 without prejudice.

Please add new claims 36-53 as follows.

--36. A method of inhibiting replication of a respiratory syncytial virus in a respiratory cell, comprising delivering a nucleic acid molecule encoding $\alpha_1$ antitrypsin to a population of cells, wherein the population comprises a respiratory cell that has been infected by a respiratory syncytial virus or that will be infected by a respiratory syncytial virus, wherein a cell in the population produces $\alpha_1$ antitrypsin encoded by the nucleic acid molecule, thereby inhibiting replication of the respiratory syncytial virus in the respiratory cell.

37. The method of claim 36, wherein the nucleic acid molecule encoding $\alpha_1$ antitrypsin is associated with a positively charged liposome.

38. The method of claim 37, wherein the positively charged liposome is Lipofectin™.

39. The method of claim 36, wherein the respiratory cell is a nasal mucosal cell or a lung epithelial cell.

40. The method of claim 36, wherein the $\alpha_1$ antitrypsin is human $\alpha_1$ antitrypsin.

41. The method of claim 36, wherein the nucleic acid molecule encoding $\alpha_1$ antitrypsin is

a DNA molecule in operable association with a promoter.

42. A method of reducing respiratory syncytial virus infectivity in a population of cells, comprising delivering a nucleic acid molecule encoding $\alpha_1$ antitrypsin to a population of cells, wherein the population has been exposed to respiratory syncytial virus or will be exposed to respiratory syncytial virus, wherein a cell in the population produces $\alpha_1$ antitrypsin encoded by the nucleic acid molecule, thereby reducing respiratory syncytial virus infectivity in a population of cells.

43. The method of claim 42, wherein the nucleic acid molecule encoding $\alpha_1$ antitrypsin is associated with a positively charged liposome.

44. The method of claim 43, wherein the positively charged liposome is Lipofectin™.

45. The method of claim 43, wherein the respiratory cell is a nasal mucosal cell or a lung epithelial cell.

46. The method of claim 43, wherein the $\alpha_1$ antitrypsin is human $\alpha_1$ antitrypsin.

47. The method of claim 43, wherein the nucleic acid molecule encoding $\alpha_1$ antitrypsin is a DNA molecule in operable association with a promoter.

48. A method of inhibiting infection of a respiratory cell by a respiratory syncytial virus, comprising delivering a nucleic acid molecule encoding $\alpha_1$ antitrypsin to a population of cells that includes the respiratory cell, wherein the respiratory cell has been exposed to respiratory syncytial virus or will be exposed to respiratory syncytial virus, wherein a cell in the population produces $\alpha_1$ antitrypsin encoded by the nucleic acid molecule, thereby inhibiting infection of the

respiratory cell by the respiratory syncytial virus.

49. The method of claim 48, wherein the nucleic acid molecule encoding $\alpha_1$ antitrypsin is associated with a positively charged liposome.

50. The method of claim 49, wherein the positively charged liposome is Lipofectin™.

51. The method of claim 48, wherein the respiratory cell is a nasal mucosal cell or a lung epithelial cell.

52. The method of claim 48, wherein the $\alpha_1$ antitrypsin is human $\alpha_1$ antitrypsin.

53. The method of claim 48, wherein the nucleic acid molecule encoding $\alpha_1$ antitrypsin is a DNA molecule in operable association with a promoter.--

REMARKS

Support for claims 36 through 53 may be found, e.g., at page 5, lines 4-7; page 22, line 24, through page 23, line 1; page 26, lines 9, through page 27, line 1; and page 31, lines 20-27, of the specification; and in the overall teachings of the originally filed claims and the specification as a whole. It is believed that no new matter has been added by the above new claims.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail Invoice No. EL 491883896US in an envelope addressed to: BOX PATENT APPLICATION, Commissioner for Patents, Washington, D C 20231, on this 20th day of December, 2001

Erick Calderon

Date 12/20/01